

REMARKS

Claims 2 and 3 have been rejected by the Examiner under 35 USC 103(a) as being obvious over Pangsrivongse (Rev. Filipina Med. Farm, 1938 - CAPLUS abstract), the admitted state of the art, and the reference entitled "Thailand: Thai Equivalent Viagra Drug Unveiled" (source: Nation - PROMT Newsletter Abstract, March 24, 1999), in view of Pope (GB 785,987). This rejection is respectfully traversed.

The present invention is directed to a method of treating erection dysfunction or malfunction wherein a pharmaceutically acceptable amount of an extract is administered to a male patient with erection dysfunction or malfunction wherein said extract is a mixture prepared by the steps of drying tubers, roots, stems, leaves and/or tissue cultured calluses of *Butea Superba* and *Mucuna Collettii*. According to the present invention it has been unexpectedly found that a greater therapeutical effect on erection dysfunction or malfunction is obtained when a mixed extract of *Butea Superba* and *Mucuna Collettii* is used in combination compared to the use of the extracts alone. As the Examiner will note, claim 2 is proposed to be amended such that claim 2 now recites that the extract is a mixture of *Butea Superba* and *Mucuna Collettii*. Accordingly, the Applicants have on hand experimental data which clearly shows that a greater therapeutic effect erection dysfunction or malfunction can be achieved when using a mixed extract of *Butea Superba* and *Mucuna Collettii*, particularly extracts of leaves and calluses of *Butea Superba* and *Mucuna Collettii*. Accordingly, attached to the present amendment is the experimental data which clearly shows the remarkably greater therapeutic effect on erection dysfunction or malfunction when *Butea Superba* is used in combination with *Mucuna Collettii* compared to when using either one of these materials alone.

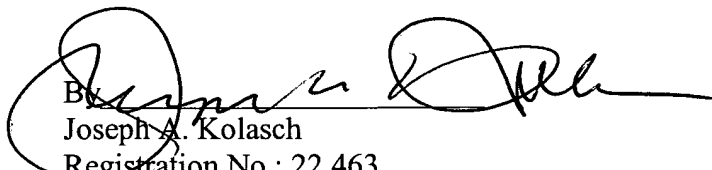
Although the experimental data has not been submitted in the form of a Declaration under 37 CFR 1.132, it is readily apparent that such a declaration can be readily submitted upon the request of the Examiner.

It is recognized that the present proposed Amendment may not be entered by the Examiner because of the possibility of raising new issues in connection with the prosecution of the present application. If this be the case, the Applicant intends to file an RCE application using the non-entry of the proposed Amendment as the basis for the filing of the RCE application, and including with the RCE application a Declaration Under 37 CFR 1.132 presenting the experimental data in the proper format.

Accordingly, in view of the above amendment and remarks reconsideration of the rejection and allowance of claims 2 and 3 of the present application are respectfully requested. In the event that the proposed Amendment does not place the present application into condition for allowance, entry thereof is respectfully requested to place the present application into better condition for appeal.

Respectfully submitted,

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Experimental Data

- Effects by parts of Butea superba -

1. Preparation of extracts by parts of Butea superba

each 100g of the tubers, stems, leaves and tissue-cultured calluses of Butea superba were cleansed, dried at 70°C for about 5 hours by use of a hot-air drier, and pulverized. To the resulting plant pieces were added 50mL of a mixture of methanol and water (80/20 v/v), followed by the extraction at 50°C for about 6 hours. After being filtered, the extracts were concentrated in a vacuum to remove the solvent. The concentrates were freeze-dried leaving powders of each extracts by parts of Butea superba.

2. Effects by parts of Butea superba on male with erection dysfunction upon oral administration

In order to determine whether the extracts by parts of Butea superba, e.g., each extracts of tubers, stems, leaves and tissue-cultured calluses of Butea superba have an effect on erection dysfunction, 150 male patients with erection dysfunction, who were 20~55 years old, were orally administrated a placebo, extract of tubers of Butea superba, extract of stems of Butea superba, extract of leaves of Butea superba, or extract of tissue-cultured calluses of Butea superba. It was used tapioca starch as the placebo.

150 males divided into 5 groups with 30 males. The five groups were administrated with the placebo, extract of tubers of Butea superba, extract of stems of Butea superba, extract of leaves of Butea superba, or extract of tissue-cultured calluses of Butea superba as following Table 1. The amount of administration was divided into two equal parts and administrated twice a day, e.g., after breakfast and supper. The period of experiment was two months. The results are given in Table 2 as below.

【Table 1】

Group No.	Administration contents
Group 1	placebo 400mg/day
Group 2	extract of tubers of Butea superba 400mg/day
Group 3	extract of stems of Butea superba 400mg/day
Group 4	extract of leaves of Butea superba 400mg/day
Group 5	extract of tissue-cultured calluses of Butea superba 400mg/day

【Table 2】

	Group 1	Group 2	Group 3	Group 4	Group 5
No. of Subjects	30	30	30	30	30
1 st Erection Day after administration (day) (mean \pm S.D.)	30	7.39 \pm 1.05	8.12 \pm 0.85	7.42 \pm 0.81	6.92 \pm 0.74
Immediate Erection	30	19	18	19	20
Continuous Erection	30	18	18	19	19
Erection Maintenance for 2 mins. after Ejaculation	30	8	8	7	9
Weekly frequency of erection/ remarkably increasing	30	21	17	19	18
Weekly Nos. of intercourse/ remarkably increasing	30	9	8	10	9
Satisfaction in sexual activity	30	21	20	19	20

According to the above results of Table 2, it was confirmed that each extracts by parts of *Butea superba* had great therapeutic effects on erection dysfunction or malfunction.

3. Effects by parts of *Butea superba* on male with erection dysfunction upon topical application

It was determined whether gels containing the extracts by parts of *Butea superba* have an effect on erection dysfunction on 150 male patients with erection dysfunction, who were 20~55 years old.

150 males divided into 5 groups with 30 males. The five groups were applied to the penis with the gel containing no any extract; and gels containing extract of tubers of *Butea superba*, extract of stems of *Butea superba*, extract of leaves of *Butea superba*, and extract of tissue-cultured calluses of *Butea superba* as following Table 3. The amount of application was divided into two equal parts and applied to the penis twice a day, e.g., morning and night. The period of experiment was one month. The results are given in Table 4 as below.

【Table 3】

Group No.	Extract contained in gel
Group 1	Not contained
Group 2	extract of tubers of <i>Butea superba</i> 400mg/ day
Group 3	extract of stems of <i>Butea superba</i> 400mg/ day
Group 4	extract of leaves of <i>Butea superba</i> 400mg/ day
Group 5	extract of tissue-cultured calluses of <i>Butea superba</i> 400mg/ day

【Table 4】

Group No.	Total No. of Subjects	No. of Restored Male
Group 1	30	1
Group 2	30	19
Group 3	30	18
Group 4	30	16
Group 5	30	20

4. Cutaneous allergy assay of extracts by parts of *Butea superba*

For cutaneous allergy assay, the extracts by parts of *Butea superba* were applied to the skin of six rats respectively. The results are given in Table 5 as below.

【Table 5】

	Parts of <i>Butea superba</i>			
	tubers	stems	leaves	calluses
1 st Allegic Response	No	No	No	No
2 nd Allegic Response	No	No	No	No



Experimental Data

- When mixing *Butea superba* and *Mucuna collettii* -

1. Preparation of extract of *Butea superba*

100g of the tuber of *Butea superba* was cleansed, dried at 70°C for about 5 hours by use of a hot-air drier, and pulverized. To the resulting plant pieces was added 50mL of a mixture of methanol and water (80/20 v/v), followed by the extraction at 50°C for about 6 hours. After being filtered, the extract was concentrated in a vacuum to remove the solvent. The concentrate was freeze-dried leaving powder of extract of *Butea superba*.

2. Preparation of extract of *Mucuna collettii*

100g of the tuber of *Mucuna collettii* was cleansed, dried at 70°C for about 5 hours by use of a hot-air drier, and pulverized. To the resulting plant pieces was added 50mL of a mixture of methanol and water (80/20 v/v), followed by the extraction at 50°C for about 6 hours. After being filtered, the extract was concentrated in a vacuum to remove the solvent. The concentrate was freeze-dried leaving powder of extract of *Mucuna collettii*.

3. Effect of *Butea superba*, *Mucuna collettii* and combination thereof on male with erection dysfunction upon oral administration

In order to determine whether the extracts of *Butea superba*, *Mucuna collettii* and combination thereof have an effect on erection dysfunction, 180 male patients with erection dysfunction, who were 20~55 years old, were orally administered a placebo, extract of *Butea superba*, extract of *Mucuna collettii*, or combination of extract of *Butea superba* and extract of *Mucuna collettii*. It was used tapioca starch as the placebo.

180 males divided into 6 groups with 30 males. Each groups were administered with the placebo, extract of *Butea superba*, extract of *Mucuna collettii*, or combination of extract of *Butea superba* and extract of *Mucuna collettii* as following Table 1. The amount of administration was divided into two equal parts and administered twice a day, e.g., after breakfast and supper. The period of experiment was two months. The results are given in Table 2 as below.

【Table 1】

Group No.	Administration contents		
	placebo	Butea superba	Mucuna collettii
1	400mg/ day	-	-
2	-	400mg/ day	-
3	-	300mg/ day	100mg/ day
4	-	200mg/ day	200mg/ day
5	-	100mg/ day	300mg/ day
6	-	-	400mg/ day

【Table 2】

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
No. of Subjects	30	30	30	30	30	30
1 st Erection Day after administration (day) (mean \pm S.D.)	30	7.39 \pm 1.05	4.23 \pm 0.89	2.19 \pm 0.74	4.56 \pm 0.92	9.51 \pm 1.20
Immediate Erection	30	21	24	28	23	19
Continuous Erection	30	18	23	27	21	15
Erection Maintenance for 2 mins. after Ejaculation	30	9	13	20	12	7
Weekly frequency of erection/ remarkably increaing	30	20	24	27	22	16
Weekly Nos. of intercourse/ remarkably increaing	30	7	10	16	9	5
Satisfaction in sexual activity	30	22	26	29	24	19

There was obtained a remarkably greater therapeutic effect on erection dysfunction or malfunction when Butea superba was used in combination with Mucuna collettii than alone.

4. Effect of Butea superba, Mucuna collettii and combination thereof on male with erection dysfunction upon topical application

It was determined whether gels containing the extracts of Butea superba, Mucuna collettii and combination thereof have an effect on erection dysfunction on 180 male patients with erection dysfunction, who were 20~55 years old.

180 males divided into 6 groups with 30 males. Each groups were applied to the penis with the gel containing no any extract; and gels containing extract of Butea superba, extract of Mucuna collettii, and combination of extract of Butea superba and extract of

Mucuna collettii as following Table 3. The amount of application was divided into two equal parts and applied to the penis twice a day, e.g., morning and night. The period of experiment was one month. The results are given in Table 4 as below.

【Table 3】

Group No.	Extract contained in gel	
	<i>Butea superba</i>	<i>Mucuna collettii</i>
Group 1	-	-
Group 2	400mg/ day	-
Group 3	300mg/ day	100mg/ day
Group 4	200mg/ day	200mg/ day
Group 5	100mg/ day	300mg/ day
Group 6	-	400mg/ day

【Table 4】

Group No.	Total No. of Subjects	No. of Restored Male
Group 1	30	1
Group 2	30	19
Group 3	30	23
Group 4	30	27
Group 5	30	22
Group 6	30	16

5. Cutaneous allergy assay of *Butea superba* and *Mucuna collettii*

For cutaneous allergy assay, the extracts of *Butea superba* and *Mucuna collettii* were applied to the skin of six rats respectively. The results are given in Table 5 as below.

【Table 5】

	<i>Butea superba</i>	<i>Mucuna collettii</i>
1 st Allegic Response	No	No
2 nd Allegic Response	No	No